PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GWS/PG/24287	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/00702	International filing date *(day/month/year)* 19.02.2003	Priority date *(day/month/year)* 19.02.2002
International Patent Classification (IPC) or both national classification and IPC A61L2/00		
Applicant RESOLUTION CHEMICALS LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the opinion
   II ☐ Priority
   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.08.2003	02.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Marti, P Telephone No. +49 89 2399-7858

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/00702

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-17	as published

Claims, Numbers

1-17	received on 29.12.2003 with letter of 23.12.2003
18, 19	filed with telefax on 21.05.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-17
	No:	Claims	18,19
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-17
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Document WO 96 32095 (D1) discloses a method for producing a pharmaceutical composition for inhalation. A non-sterile steroid (e.g. budesonide, fluticasone, see p. 5, l. 12-16) is dissolved in a solvent (e.g. an alcohol, see p. 6, l. 5-17), the solution is passed through a filter having pores of 10-160 microns (see page 6, lines 24-26) and combined with water (anti-solvent) to form a suspension. The suspension is treated (= by stirring or using ultrasound waves, see page 7, lines 3-5) to obtain a particle size distribution having a mass median less than 10 microns (see page 3, lines 23-25). The size of the particles obtained according to the process of D1 may be controlled by adjusting the process parameters such as the rate of agitation. It should be noted that present claim 1 does not specify that the treatment of the suspension should be carried out after the formation of the suspension is completed.
Further, D1 mentions that the suspension **may be** dried in conventional manner and agglomerated **if desired** (see page 7, lines 7-9).

The method defined in present claim 1 differs from the method disclosed in D1 in that the solution is filtered to yield a sterile solution. The technical problem to be solved by claim 1 with respect to D1 is therefore the provision of a sterile suspension.

The sterilisation of pharmaceutical powders by preparing a solution which is then filtrated to obtain a sterile solution, is well known in the art. For example, document US-A-4105550 (D5) discloses a method of preparing sterile pharmaceutical products. The substance to be sterilised is dissolved in a solvent and the resulting solution is subjected to a sterilising filtration.
A skilled person looking for a way to solve the above mentioned problem would obviously consider the teaching of D5 in order to arrive at the proposed solution, i.e. to replace the filter of D1 by a sterilising filter.

Hence, the subject-matter of claim 1 does not involve an inventive step in the light of the disclosures of D1 and D5 (Art. 33.3 PCT).

2. Document D5 discloses an apparatus for preparing a sterile pharmaceutical composition. The apparatus comprises a container (= presterilised precipitation tank, 3) defining a sterile inner compartment, a sterilising filter (2), a vessel for containing the solvent and a vessel for containing the non-sterile product (not shown but described on col. 3, lines 22-24), arranged so that the solvent can be combined with the product to yield a solution, and the solution then filtered to yield a sterile solution. In the container the solution is brought in contact with a precipitating medium.
Note that the fact that claim 18 is directed to an apparatus for preparing a sterile pharmaceutical composition of a **steroid according to the method of claim 1**, does not restrict the claim over the disclosure of D5, then the use is not an apparatus feature. The apparatus of D5 is suitable for preparing a sterile pharmaceutical composition of a steroid according to the method of claim 1. Consequently, all the features of the apparatus defined in present claim 18 are disclosed in D5.

Therefore, document D5 is novelty destroying for the subject-matter of claim 18 (Art. 33.2 PCT).

3. Dependent claims 2-17 and 19 contain features which either are disclosed in the cited documents or fall within the customary practice followed by persons skilled in the art and do not involve an inventive step as no particular or unexpected effect is apparent.

Certain observations on the international application

1. The description contains embodiments in which the step of filtering the solution to obtain a sterile solution is not mandatory. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear (Article 6 PCT).

2. At least documents D1 and D5 should be acknowledged in the description (Rule 5.1(a)(ii) PCT).